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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,826	02/09/2004	Barry N. Gellman	MIY-P03-006	9242
28120	7590	11/14/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			LUSTUSKY, SARA	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/774,826	<b>Applicant(s)</b> GELLMAN ET AL.	
	<b>Examiner</b> Sara Lustusky	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 163-171, 173-202 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 163-171, 173-202 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/13/04 9/22/04  
3/14/05 10/06/06.

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement filed 9/22/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### *Specification*

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 175-181 and 185-189** are rejected under 35 U.S.C. 102(b) as being anticipated by Adair (US 5336231).

5. Adair teaches a system (as seen in Figures 28-37) capable of treating urinary incontinence comprising:

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- a. a shaft (92) having a curved portion (93) and an interlocking mating structure (96) on a distal end of the shaft (92); and
- b. a sling assembly (90) having an end for receiving the distal end of the shaft (92), and a complementary interlocking mating structure (84);
- c. wherein the interlocking mating structure (96) of the shaft (92) is inserted into the complementary interlocking mating structure (84) of the sling assembly (90);
- d. wherein the mating structures (96, 84) are releasably lockable such that the shaft (92) is releasable lockable to the sling assembly (90);
- e. wherein the sling assembly (90) is indirectly connected to the shaft (92) and the complementary mating structure (84) is indirectly connected to the sling assembly (90); and
- f. wherein the sling assembly (90) comprises a sling (82).

6. **Claims 193-199** are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 4935027).

7. Yoon teaches a system (as seen in Figures 1, 1E and 2A-10) capable of treating urinary incontinence comprising:

- a. a handle (20);
- b. a shaft (24a,b) attached to the handle (20) and having a channel (32) located at an end and a curved portion (as seen in Figure 1); and

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- c. a sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) having an end for associating with the channel (32) of the shaft (24a,b),
- d. wherein the channel (32) is releasable lockable for locking the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) in the channel (32) (as described in lines 21-23, 57-58 of column 6, lines 1-19, 34-39, 60-68 of column 7 and lines 1-4 of column 8);
- e. wherein the system further comprises a spring loaded locking mechanism (44, 150) for locking the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) in the channel (32);
- f. wherein the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) comprises an elongated extension located at the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>);
- g. wherein the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) comprises a sling (as described in lines 9-11 of column 2);
- h. wherein in an alternate embodiment, the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) further comprises an aperture (as seen through 210) located at the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) for advancing the sling assembly through the shaft (24b) (as seen in Figure 1E).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 182-184 and 190-192** are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5336231) as applied to claims 175 and 185 above, in view of Wilkinson et al. (US 3580256).

9. Adair teaches a system capable of treating urinary incontinence comprising a shaft with a curved portion and a sling assembly, wherein both the shaft and the sling assembly have interlocking mating structures, as described above. However, the use of a pouch over any portion of the sling assembly is not taught.

10. Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

11. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Adair because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

12. **Claims 163-171 and 173-174** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 4935027) in view of Wilkinson et al. (US 3580256).

13. Yoon teaches a system (as seen in Figures 1, 1E and 2A-10) capable of treating urinary incontinence comprising:

a. a handle (20);

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- b. a shaft (24a,b) attached to the handle (20) and having a channel (32) located at an end and a curved portion (as seen in Figure 1); and
  - c. a sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) having an end for associating with the channel (32) of the shaft (24a,b),
  - d. wherein the channel (32) is releasable lockable for locking the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) in the channel (32) (as described in lines 21-23, 57-58 of column 6, lines 1-19, 34-39, 60-68 of column 7 and lines 1-4 of column 8);
  - e. wherein the system further comprises a spring loaded locking mechanism (44, 150) for locking the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) in the channel (32);
  - f. wherein the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) comprises an elongated extension located at the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>);
  - g. wherein the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) comprises a sling (as described in lines 9-11 of column 2);
  - h. wherein in an alternate embodiment, the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) further comprises an aperture (as seen through 210) located at the end of the sling assembly (30, 30<sub>o</sub>, 30<sub>i</sub>) for advancing the sling assembly through the shaft (24b) (as seen in Figure 1E).
14. While Yoon teaches that the sling assembly material comprises materials commonly used in the art, the use of a pouch over any portion of the sling assembly is not taught.



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15. Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Yoon because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

14. **Claims 200-202** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 4935027) as applied to claim 193 above in view of Wilkinson et al. (US 3580256).

15. Yoon teaches a system capable of treating urinary incontinence comprising: a handle, a shaft having a channel and a curved portion, and a sling assembly, as described above. While Yoon teaches that the sling assembly material comprises materials commonly used in the art, the use of a pouch over any portion of the sling assembly is not taught.

17. Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

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18. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Yoon because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yoon (US 5665096) teaches a surgical instrument comprising a shaft, a sling assembly and a handle. Blake et al. (US 5647836) teaches the use of sutures and slings to treat urinary incontinence. Hlavacek et al. (US 4792336) and Chin (US 5391182) teach the use of sling and suture material that is deformable and substantially flat.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*S.L.*

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11/09/06



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